IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SWISHER INTERNATIONAL, INC., Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 1:22-cv-954-CRC

BRIEF OF PUBLIC HEALTH AND MEDICAL ORGANIZATION AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

Pursuant to LCvR 7(o)(5) and Fed. R. App. P. 29(a)(4)(A), *amici curiae* are all non-profit organizations committed to advancing the public health. None of the *amici* has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the *amici*.

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Amici medical and public health organizations submit this brief in support of Defendants and urge the Court to grant Defendants' cross-motion for summary judgment and to deny the summary judgment motion filed by Plaintiff Swisher International, Inc. ("Swisher").

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative. *Amici* are non-profit organizations that have worked for decades to protect the public from the devastating harms caused by tobacco products, which are the leading cause of preventable death in America, claiming over 480,000 lives every year.

Amici have a strong interest in ensuring that cigars introduced to the market after February 2007—which are considered "new tobacco products" under the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 et. seq. (2009) ("TCA")—do not increase the risk to public health and especially to children. That compelling public health interest can only be assured by subjecting these products to the same premarket review requirements and standards that the TCA applies to cigarettes and other tobacco products. *Amici* seek to protect the public from the serious, adverse health effects of cigars, given the severe risk of disease from smoking cigars; their addictiveness; cigar manufacturers' growing use of marketing strategies that appeal to young people; and persistently high rates of cigar smoking by young people. Accordingly, *amici* oppose Swisher's request to enjoin FDA from enforcing the premarket review requirements of the TCA. Such relief would harm public health by prolonging the period during which Swisher's

[1] No counsel for any party authored this brief in whole or in part, neither the parties nor their counsel contributed money that was intended to fund preparing or submitting this brief, and no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief. *See* LCvR 7(o)(5); Fed. R. App. P. 29(a)(4)(E).

highly addictive and toxic flavored cigars remain on the market without completion of the required regulatory review by the United States Food & Drug Administration ("FDA").

Amici also have a special interest in this case because they are plaintiffs in *American Academy of Pediatrics v. FDA* ("*AAP*"), in which they obtained a federal court order: (1) vacating the FDA's 2017 guidance that suspended the operation of premarket review for cigars for several years, thus granting cigar companies like Swisher an unlawful "regulatory holiday," in the words of the *AAP* court, (2) establishing new deadlines for submission of premarket applications, and (3) limiting the time period that new cigars may remain on the market without the required premarket orders. 379 F. Supp. 3d 461, 493 (D. Md. 2019); 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020). Because the relief sought by Swisher would improperly undermine the *AAP* order, *amici* have a strong interest in opposing it.

SUMMARY OF THE ARGUMENT

The Tobacco Control Act and the 2016 Deeming Rule require that Swisher obtain an FDA "substantial equivalence" order *before* Swisher may continue commercial marketing of cigar products it introduced in the United States after February 15, 2007. Since 2010, Swisher has known that to obtain such an order, FDA would require it to demonstrate that its products do not raise new questions of public health and yet Swisher did not undertake the studies necessary to demonstrate that its products met this standard until 2018. Nevertheless, since 2016, due to the FDA's exercise of enforcement discretion, Swisher has enjoyed years of selling its deadly, addictive cigars even though it never obtained regulatory authorization. And Swisher has taken full advantage of its regulatory "holiday": transforming the cigar market with the introduction of

cigarillos and other cigars[2] in flavors known to appeal to youth, selling them cheaply (such as two cigars for 99 cents) and in flashy packaging that young people prefer, and marketing them using social media, entertainment, and athletic celebrities that youth follow.

In this litigation, Swisher asks the Court to enjoin FDA from enforcing the premarket review provisions of the TCA so that it may continue marketing its cigars for an indefinite period without the regulatory authorization required by law. It alleges that FDA has unreasonably delayed in acting on Swisher's substantial equivalence reports and that FDA's threat of enforcement deprives Swisher of fair notice. Pl's. Mot. Summ. J. & Supp. Mem. of Law ("Pl's. Mot.") 20-34, ECF 104. Swisher contends that it could face enforcement against its unauthorized products because FDA has not yet decided Swisher's substantial equivalence reports, which Swisher did not file until shortly before the September 9, 2020 filing deadline. Swisher also makes various claims about the Deeming Rule itself, *see* Pl's. Mot. 34-50, which as the Government notes, are precluded by the doctrine of *res judicata*. *See* Mem. Supp. Defs'. Mot. Leave Amend Answer 13-18, ECF 106-1.

To avoid duplication of the Government's brief, *amici* focus on two of the flaws in Swisher's arguments for injunctive relief. First, Swisher's requested relief would give it continued relief from the TCA for an indefinite period until FDA decides its substantial equivalence applications, thus allowing it to continue selling its deadly tobacco products even though it has not met the statutory standards. This is contrary to the statute and would undermine the order of the *AAP* court. Second, any harm to Swisher is largely of its own making and is far outweighed by the

[2] This brief adopts FDA's definition of the term "cigar," which includes smaller cigars such as cigarillos. 21 C.F.R. § 1143.1 ("Cigar means a tobacco product that: (1) Is not a cigarette and (2) Is a Roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.").

well-established public health harms, particularly to youth, that would result if Swisher's flavored cigars are allowed to remain on the market without the required FDA authorization.

STATUTORY AND REGULATORY BACKGROUND

As the Supreme Court has declared, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). In 2009, Congress responded to this threat by enacting the TCA to give broad authority to the FDA to regulate tobacco products and curb the predatory conduct of the tobacco industry.

In enacting the TCA, Congress found that the "lack of government regulation has allowed the tobacco industry to design new products or modify existing ones in ways that increase their appeal to children and that contribute to the risk and incidence of disease." H.R. REP. NO. 111-58, pt. 1, at 4 (2009). To combat that harmful activity, Congress established a premarket review framework to ensure that the FDA evaluated new tobacco products before they entered the market. As a general matter, Congress allowed a manufacturer to market a "new" tobacco product (i.e., a product introduced into commerce after February 15, 2007) only if it could demonstrate that the product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). No cigar can meet this "public health" standard since, as FDA has found, "[c]igars are associated with significant risk and provide no public health benefit."[3]

Instead, to bring a new cigar to market lawfully, a cigar manufacturer must pursue an alternative pathway by submitting a report demonstrating that the new product is "substantially equivalent" to a product that was on the market as of February 2007 (i.e., "a pre-existing tobacco product"). To receive authorization, the Report must demonstrate that the new product has the

[3] FDA, Draft Guidance, *Modifications to Compliance Policy for Certain Deemed Tobacco Products*, at 16 (Mar. 2019), https://www.regulations.gov/document/FDA-2019-D-0661-0003.

"same characteristics" as a pre-existing tobacco product or that it does not "raise different questions of public health." 21 U.S.C. § 387j(a)(2) & (a)(3). Generally speaking, any new cigar product on the market without an FDA order establishing its "substantial equivalence" is adulterated and misbranded and subject to FDA enforcement. *See* 21 U.S.C. §§ 387(b)(6), 387(c)(a)(6).[4] Thus, the "substantial equivalence" pathway ensures that the FDA has the information needed, and the opportunity, to evaluate proposed changes in cigar products that increase their appeal, addictiveness, or toxicity, or that otherwise raise "different questions of public health." As the D.C. Circuit observed in *Nicopure Labs, LLC. v. FDA*, "Congress . . . took the then-current tobacco product market as a baseline from which to ratchet down tobacco products' harms to public health." 944 F.3d 267, 271 (D.C. Cir. 2019).

The TCA gave the FDA initial regulatory authority over cigarettes and certain other tobacco products; it also gave the agency the authority to extend its jurisdiction over all tobacco products, including cigars, by issuing a rule "deeming" them subject to its authority. That occurred by virtue of the issuance of the final Deeming Rule, effective in August 2016. *See* 81 Fed. Reg. 28, 974 (May 10, 2016). As a result of the Deeming Rule, in 2016 new cigar products became subject to FDA enforcement as "adulterated" and "misbranded" products because they lacked FDA orders finding them "substantially equivalent" to pre-existing tobacco products. 21 U.S.C. §§ 387(b)(6), 387(c)(a)(6). There is no right under the TCA for a new product to be on the market without a marketing order or a substantial equivalence determination; the newly deemed products (primarily cigars and e-cigarettes) have been on the market only through the enforcement forbearance of the FDA.

[4] The statute also provides for exemptions from the substantial equivalence requirement for "minor modifications" of tobacco products through the addition or deletion of a tobacco additive. 21 U.S.C. § 387e(j)(3).

In the Deeming Rule, FDA provided cigar manufacturers eighteen months from the effective date of the Rule (August 8, 2016) to file their substantial equivalence reports, i.e., until February 8, 2018, and allowed any product for which a report was submitted to remain on the market for one year thereafter. 81 Fed. Reg. at 29,011. Most of that eighteen-month compliance period had run by the time FDA, in August 2017, issued guidance that extended the period for filing a substantial equivalence report for cigars to 2021 and allowed products that applied to remain on the market until the FDA issued a decision on their report, changing the one-year post-filing grace period to a potentially indefinite exemption. *See* Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, 82 Fed. Reg. 37,459 (Aug. 10, 2017).

Amici challenged the 2017 guidance, which the U.S. District Court for the District of Maryland vacated. *AAP*, 379 F. Supp. 3d at 498. In July 2019, the court reset the lapsed February 8, 2018 deadline to May 12, 2020—giving cigar manufacturers another 10 months to prepare substantial equivalence reports, which was several months more than the manufacturers had remaining when the 2017 guidance was issued. *AAP*, 399 F. Supp. 3d at 487. The court later extended that deadline to September 9, 2020 as a result of the COVID-19 pandemic. Order, *AAP*, No. 8:18-cv-883-PGW (D. Md. Apr. 22, 2020), ECF 182. The court's remedial order also reinstated the Deeming Rule's provision that new products for which applications were timely filed could only "remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application." *AAP*, 399 F. Supp. 3d at 487. Given that the deadline for timely applications was September 9, 2020, cigars and other deemed products that lack the required premarket orders could remain on the market only until September 9, 2021 without being subject to FDA enforcement.

ARGUMENT

I. Swisher's Request to Forbid FDA Enforcement Against Its Products Would Suspend Enforcement of the TCA and Undermine the Order of a Coordinate Federal Court.

Swisher's flavored cigars that were introduced after February 15, 2007[5] are unlikely to be found substantially equivalent to pre-existing tobacco products. As explained more fully in Section II.B below, they clearly raise "different questions of public health." Yet Swisher asks the Court to exempt its cigars, for an uncertain period of time, from the statutory and regulatory regime that applies to all tobacco products.

By asking this Court to indefinitely suspend FDA enforcement with respect to its cigars, Swisher attempts an end run around the *AAP* order. As the *AAP* court found, the FDA cannot lawfully suspend enforcement of the TCA. Given the *AAP* order, neither can judicial relief in this case.

In *AAP*, *amici* challenged FDA's 2017 guidance that purported to give all e-cigarettes and cigars a blanket exemption from the TCA's authorization requirements for several years and then indefinitely thereafter until FDA ruled on their premarket or substantial equivalence applications. The court held that FDA's action was unlawful, as an "across-the-board suspension of the Tobacco Control Act's premarket approval process" was "inconsistent with the" Act because it "h[e]ld in abeyance enforcement of mandatory provisions of a statute that Congress viewed as integral to address public health dangers . . . ." *AAP*, 379 F. Supp. 3d at 492-93. The court concluded that FDA's 2017 guidance unlawfully provided tobacco manufacturers, such as Swisher, "a holiday from meeting the obligations of the law." *Id.* at 493. The court thus vacated FDA's unlawful

[5] Although Swisher claims that "most" of its "affected cigars were already on the market—often for decades—before the Deeming Rule took effect," Pl's. Mot. 10, it also admits that it made "changes" to these cigar products, making them new products under the TCA and thus subject to the TCA's premarket review requirements. *Id.* 36-37.

guidance, making clear that, while FDA had case-by-case enforcement discretion regarding violations of the Act, it could not immunize all violators altogether.[6]

The court also reinstated the Deeming Rule's provision of a date certain for the cigar makers' "holiday" from the premarket review requirements of the TCA to end, ultimately September 9, 2021. *See AAP*, 399 F. Supp. 3d at 487; Order, *AAP*, No. 8:18-cv-883-PGW, ECF 182. FDA may now exempt new products from the Act's filing requirements only "for good cause on a case-by-case basis." *AAP*, 399 F. Supp. 3d at 487.

Swisher's request for an order "enjoin[ing] the FDA from taking enforcement actions against any Swisher product with a pending substantial-equivalence report," Pl's. Mot. 3; *see also id.* 2, represents a collateral attack on the *AAP* decision. The Middle District of Florida recognized as much when it denied Swisher's motion for a preliminary injunction: "If anything affected Swisher's rights, it was the decision in *AAP* to vacate the FDA's guidance that gave Swisher exactly what it now asks this Court to do." ECF 48 at 13.

What Swisher calls FDA's "threats of enforcement" are nothing more than requirements of the TCA as reflected in the District of Maryland's holding in the *AAP* case: anybody selling new tobacco products without a marketing or substantial equivalence order is acting unlawfully. The only purported "threat" Swisher describes is the agency's statement that "manufacturers . . . 'risk[ed] FDA enforcement' if they marketed unapproved products after September 9, 2021." Pl's. Mot. 15 (quoting Tr. at 20, *Deemed Product Review: A Conversation with the Center for Tobacco*

[6] Swisher's depiction of *AAP* misleadingly omits *AAP*'s holding that the regulatory exemption "holiday" provided by the FDA—the holiday Swisher would have this Court extend—is "inconsistent with the Tobacco Control Act and in excess of [FDA's] statutory authority…." *AAP*, 379 F. Supp. 3d at 494. Rather, Swisher repeatedly describes the *AAP* decision as merely "vacat[ing] the August 2017 guidance for lack of notice and comment…." Pl's. Mot. 31; *see also id.* 13. .

Products Office of Science (June 11, 2021), https://www.fda.gov/media/150275/download). Far from being a "threat," this statement merely reflects the plain meaning of the statutory text, which the *AAP* court and other courts have also recognized: "An order . . . *is required*" before a new tobacco product may be lawfully marketed. 21 U.S.C. § 387j(a)(2)(A) (emphasis added); *see also AAP*, 379 F. Supp. 3d at 470 ("The Act requires" manufacturers to "obtain premarket authorization before marketing new products."); *Nicopure*, 944 F.3d at 281 ("The premarket approval requirement is in the Act. It was Congress, not the FDA, that imposed it on new tobacco products . . . ."). An agency does not act unlawfully by recognizing clear and settled law and the dictates of a standing court order.

Moreover, if this Court were to grant Swisher's requested relief, any similarly situated company would be eligible for the same relief, resulting in a massive and indefinite exemption from premarket review for large swaths of the cigar industry, if not the tobacco industry as a whole. Such an extra-statutory regulatory holiday would be plainly impermissible and would jeopardize public health. *See Nicopure*, 944 F.3d at 281; *AAP*, 379 F. Supp. 3d at 492-93.

Indeed, a previous attempt by Swisher's trade association to enjoin the FDA from enforcing the premarket review requirements was rejected by this Court in *Cigar Association of America v. FDA*, No. 16-cv-1460, 2020 WL 5231335 (D.D.C. Sept. 2, 2020). The Cigar Association of America is a trade association of which Swisher is a member, whose board of directors includes three Swisher executives, and whose Board Chairman was Swisher's President at the time this suit was initiated. *See* Mem. Supp. Defs'. Mot. Leave Amend Answer 3, ECF 106-1. In that case, the Cigar Association sought an injunction to prevent enforcement of the TCA's premarket review requirements pending appeal of a decision granting summary judgment against various attacks against the Deeming Rule (including many of the arguments Swisher makes here). The court

denied the injunction:

> The injunctive relief requested here would upset the *AAP* court's judgment without justification. It would, in the short term, exempt from the *AAP* court's order all newly deemed cigar and pipe tobacco products. Such collateral relief from another court's order is generally unwarranted . . . . It would be inequitable for this court to undo, even temporarily, the hard-fought victory achieved by the plaintiffs in *AAP*. The *AAP* plaintiffs' interests, avoiding an unnecessary conflict with the *AAP* court's decision, and the public's interest in enforcing the *AAP* court's remedial order, all counsel strongly against injunctive relief pending appeal.

Cigar Ass'n of Am., 2020 WL 5231335 at *1. These same reasons counsel against the injunction Swisher seeks here.

Swisher points to *PHH Corporation v. Consumer Financial Protection Bureau*, 839 F.3d 1 (D.C. Cir. 2016), to support its request for an injunction on the ground that FDA failed to provide fair notice. Pl's. Mot. 30, 31, 34. But far from aiding Swisher, *PHH* illustrates its overreach. In *PHH*, an agency reversed a prior interpretation of a statute and sought to apply the new interpretation retroactively. 839 F.3d. at 46-49. The D.C. Circuit held that this violated "[t]he Due Process Clause [which] limits the extent to which the Government may *retroactively* alter the legal consequences of an entity's or person's *past conduct*." *Id.* at 46 (emphasis added). *PHH* turned on "anti-retroactivity principles," *id.* at 48, not *prospective* application. *See, e.g.*, *id.* at 47 ("An 'agency should not change an interpretation in an adjudicative proceeding where doing so would impose new liability on individuals for past actions which were taken in good-faith reliance on agency pronouncements.'") (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156-57 (2012))). Indeed, *PHH* expressly distinguished the retroactive liability before it from the commonplace situation, such as the present case, of "expect[ing] regulated parties to conform their conduct to an agency's interpretations once the agency announces them." *Id.* (quoting *SmithKline*, 567 U.S. at 159).

This case is very different from *PHH*. FDA has not threatened to impose liability for the period in which Swisher was marketing its products pursuant to FDA's explicit promise of forbearance. Rather, FDA has merely declined to provide immunity for *future* marketing that is inconsistent with the plain requirements of the law and the order of a federal court. Swisher contends that it should be allowed to break the law *prospectively* with impunity—based largely on prior assurances that were held unlawful by the *AAP* court. This unprecedented claim should be rejected.

II. Any Harm to Swisher Is of Its Own Making and Is Far Outweighed by the Harm to Public Health That Would Result from an Injunction Extending Swisher's Regulatory "Holiday."

A. Swisher has had years of notice that its products would be subject to FDA enforcement, yet delayed filing the required substantial equivalence reports.

In 2010, *ten years before Swisher submitted its substantial equivalence reports*, FDA put Swisher and other cigar manufacturers on notice that the agency planned to subject their products to the premarket review provisions of the TCA.[7] This intention was reiterated by the FDA in 2011, when the agency stated its intention to deem all "tobacco products," as defined by the TCA, subject to that Act,[8] and again in 2014 when FDA issued the proposed Deeming Rule making clear that the premarket review requirements would apply to all cigars under the proposal. *See* 79 Fed. Reg. 23,142 (Apr. 25, 2014).

[7] *See* Office of Information and Regulatory Affairs, Office of Management and Budget, *Unified Regulatory Calendar, Cigars Subject to the Family Smoking Prevention and Tobacco Control Act*, RIN No. 0910-AG38 (Spring 2010), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201004&RIN=0910-AG38.

[8] Letter from Lawrence Deyton, Dir., FDA Ctr. for Tobacco Prods., & Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation & Research, to Stakeholders re: Regulation of E-Cigarettes and Other Tobacco Products (Apr. 25, 2011), https://www.aaphp.org/Determination.

Despite this notice, Swisher admits that it did not begin to develop a testing program to provide data for submission until 2018, Amended Complaint ¶ 80, ECF 74, even though, as late as August 2017, its applications were required to be submitted by February 2018. Thus, contrary to Swisher's claim that it "dutifully complied with the FDA's guidance and submitted applications . . . under the process and timelines announced by the agency," Pl's. Mot. 1, Swisher did not even begin to develop a testing program for its products until eight years after it knew it would eventually be subject to the premarket provisions of the TCA, four years after the FDA formally proposed to issue a rule extending its jurisdiction over cigars, and likely after the deadline for substantial equivalence reports established by the final Deeming Rule.

Moreover, Swisher did not file its substantial equivalence reports until days before the September 9, 2020 deadline set by the Maryland federal court, *see* Johnson-Malden Decl. ¶ 31, ECF 2-2, despite its understanding that "virtually all of its cigars qualify as new tobacco products . . . subject to the Act's premarket review provisions . . . ." *Id.* ¶ 13. There is no reason Swisher, or any other cigar manufacturer, need have waited until September 2020 to file substantial equivalence reports. Indeed, the FDA had urged tobacco companies to make premarket filings of all kinds long before the deadlines set by the agency. As Acting FDA Commissioner Ned Sharpless stated in Fall 2019, "as I've said before, responsible manufacturers certainly don't need to wait to act. We encourage industry to use available FDA resources as a guide for their submissions to the agency . . . ."[9] As the *AAP* court observed, "manufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence reports, and exemption

[9] FDA News Release, *FDA issues proposed rule for premarket tobacco product applications as part of commitment to continuing strong oversight of e-cigarettes and other tobacco products* (Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/fda-issues-proposed-rule-premarket-tobacco-product-applications-part-commitment-continuing-strong.

requests, and if they have chosen to delay their preparations to do so, then any hardship occasioned by their now having to comply is of their own making." 379 F. Supp. 3d at 498.[10]

Indeed, the industry's failure to engage with the regulatory process was a central reason that the *AAP* court issued its remedial order in July 2019 establishing the original May 2020 application deadline. According to the court, "the record before me shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so, and it establishes a shockingly low rate of filings." *Id.* The court continued: "Thus, the record offers little assurance that, in the absence of a deadline for filing, the industry will do anything other than raise every roadblock it can and take every available dilatory measure to keep its products on the market without approval." *Id*. at 486.

Swisher has marketed its flavored cigars for years without the required FDA substantial equivalence orders—during which time it has profited handsomely at the expense of the health of the public, including children attracted to its flavored cigars. The injunction it now seeks would inappropriately and indefinitely extend the nearly decade-long regulatory "holiday" enjoyed by manufacturers of cigars and other deemed tobacco products.

B. Extending Swisher's regulatory "holiday" would harm public health.

Swisher and other cigar makers have taken full advantage of their years-long regulatory "holiday." They have introduced scores of youth-friendly flavored products that have come to

[10] In *AAP*, the cigar manufacturers made the same protestations about needing more guidance from the FDA that Swisher makes here, which the court found "disingenuous[]" due, in part, to the "lengthy guidance documents" FDA had promulgated. *AAP*, 399 F. Supp. 3d at 485. The court credited FDA's statements that "it issued final guidance concerning the SE [substantial equivalence] process in January 2011, long before the deeming rule was finalized" as well as "three versions of a frequently asked questions document concerning the SE process, most recently in December 2016." *Id.*

dominate the cigar market. As a result, Swisher's "holiday" has resulted in public health harm, particularly for children and adolescents. There is no reason to prolong indefinitely the period during which Swisher's unauthorized flavored products can continue to inflict grievous harm to public health, free of any possible FDA enforcement.

1. Since 2009, Swisher and other cigar makers have radically transformed the cigar market to appeal to children.

The TCA prohibited the marketing of flavored cigarettes other than menthol. 21 U.S.C. § 387g(a)(1). Tobacco manufacturers responded by dramatically increasing the production of small, flavored, cigarette-like cigars, transforming the cigar market. When FDA, in 2021, indicated its intention to engage in rulemaking to issue a product standard prohibiting flavors in cigars, the agency observed that, "[a]fter the 2009 statutory ban on flavors in cigarettes other than menthol, use of flavored cigars increased dramatically, suggesting that the public health goals of the flavored cigarette ban may have been undermined by continued availability of these flavored cigars."[11] Today, cigar manufacturers produce flavored cigars by the billions, lacing them with sugary flavors from candy to chocolate to lemonade.[12]

As the FDA has found, young people are far more likely than older smokers to prefer flavored cigars. *See* 79 Fed. Reg. at 23,146 ("Research has shown that . . . sugar preference is strongest among youth and youth adults and declines with age."). As one cigar manufacturer acknowledged, "[i]t is mainly new recruits to cigar smoking who take to the new flavors . . . ," and

[11] FDA News Release, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers* (Apr. 29, 2021), https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers.

[12] *See* CAMPAIGN FOR TOBACCO-FREE KIDS, NOT YOUR GRANDFATHER'S CIGAR: CHEAP AND SWEET CIGARS LURE AMERICA'S KIDS 8-11 (Oct. 4, 2023), https://www.tobaccofreekids.org/press-releases/2023_10_04_cigar-report.

it has long been the case that "new recruits" are disproportionately minors.[13] *See also* 79 Fed. Reg. at 23,155 ("Virtually all new users of most tobacco products are youth . . . ."). In connection with the release of its proposed rule to ban characterizing flavors in cigars, FDA conducted a comprehensive *Scientific Assessment of the Impact of Flavors in Cigar Products*, which concluded "that characterizing flavors in cigars are associated with increased likelihood of youth and young adult experimentation, as well as progression to more regular patterns of use."[14] These findings are reinforced with national survey data. Data from the 2018-2019 wave of the federal government's Population Assessment of Tobacco and Health ("PATH") study show that 69.2% of youth who smoked filtered cigars and 51.7% of youth who smoked cigarillos reported flavors as a reason that they smoked cigars.[15] National Youth Tobacco Survey data show that in 2023, 70.7% of high school cigar smokers used flavored cigars, with fruit being the most popular flavor.[16] More teens and young adults have initiated cigar use with a flavored cigar compared to older adults (25 years and older)[17] and likewise, teens and young adults who smoke cigars are more likely than older adult cigar smokers to use flavored cigars.[18]

As the cigar industry shifted toward the youth market, cigar sales skyrocketed. From 2000 to 2022, annual U.S. cigar consumption nearly doubled (from 6.2 to 12.8 billion sticks), while

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[13] *See No. 2 worldwide in cigars*, SWEDISH MATCH (Mar. 7, 2007), https://perma.cc/C4RW-8VC4.
[14] FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 28, (Mar. 2022), https://www.fda.gov/media/157595/download ("FDA Scientific Assessment").
[15] *Id.* at 16.
[16] Jan Birdsey et al., *Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023*, 72 MORBIDITY & MORTAL. WKLY. REP. 1173, Suppl. tbls. 2 & 3 (2023), https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7244a1-H.pdf, https://stacks.cdc.gov/view/cdc/134701 (Supp. tbl. 2), https://stacks.cdc.gov/view/cdc/134702 (Supp. tbl. 3).
[17] FDA Scientific Assessment, *supra* note 14, at 6.
[18] Cristine D. Delnevo et al., *Preference for flavoured cigar brands among youth, young adults and adults in the USA*, 24 TOBACCO CONTROL 389, 393 tbl.4 (2015), https://pubmed.ncbi.nlm.nih.gov/24721967/.

cigarette consumption declined.[19] The current cigar market has largely and increasingly consisted of mass-produced, flavored products appealing primarily to youth. Nielsen convenience store market scanner data show that the share of flavored cigars rose from 45% in 2009 to 53.3% in 2020, with sweet or candy being the most popular flavor.[20] Earlier data show that sales of flavored cigars in convenience stores increased by nearly 50% between 2008 and 2015, with the number of unique cigar flavor names more than doubling from 108 to 250.[21] Swisher has led this market shift towards youth-appealing flavored products. As it admits, "a substantial portions of Swisher's cigars" are flavored. Pl's. Mot. 28. Thus, it is unsurprising that Swisher Sweets, for example, is the third most popular cigar brand among youth ages 12 to 17.[22]

2. Swisher continues to target youth through the introduction of new flavored cigars and other youth-oriented promotional activities.

Despite the TCA's prohibition on the introduction of new cigars and other tobacco products without FDA authorization, Swisher continues to flood the market with youth-appealing flavored cigars that it advertises as "new." Thus, while Plaintiff's motion (27-28) claims that FDA's "delay has . . . locked Swisher's line of products in place" because it "cannot modify the products for which it submitted reports, nor can it introduce new products to the market," Swisher's own marketing tells a different story.

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[19] Derived from U.S. Alcohol and Tobacco Tax and Trade Bureau, Tobacco Statistics, https://www.ttb.gov/tobacco/tobacco-statistics.

[20] Cristine D. Delnevo et al., *Cigar Sales in Convenience Stores in the US, 2009-2020*, 23 J. AM. MED. ASS'N, 2429, 2430 (2021), https://jamanetwork.com/journals/jama/fullarticle/2787330.

[21] Cristine D. Delnevo et al., *Changes in the Mass-merchandise Cigar Market since the Tobacco Control Act*, 3 (Supp. 1) TOBACCO REGULATORY SCIENCE, S8, S11 (2017), https://pubmed.ncbi.nlm.nih.gov/28317004/.

[22] Derived from Substance Abuse and Mental Health Services Administration's public online data analysis system. Substance Abuse & Mental Health Data Archive, *National Survey on Drug Use and Health, 2021*, https://bit.ly/3SFEJfj (Click "Run Crosstab" to generate table).

Just since 2018, and as recently as December 2023, Swisher has introduced flavored products with no FDA marketing orders, with names like "Passion Fruit," "Purple Swish," "Coco Blue," "Maui Pineapple," and "Peppermint"—all of which come in brightly colored, kid-friendly packaging.[23]

Figure 1: Swisher Sweets (@SwisherSweets), TWITTER (July 18, 2019, 12:01 PM), https://twitter.com/SwisherSweets/status/1151884758089117697.

Figure 2: *Purple Swish*, SWISHER SWEETS, https://trade.swisher.com/purple-swish/ (last accessed Feb. 20, 2024).

[23] Swisher Sweets (@swishersweets), INSTAGRAM (Dec. 22, 2023), https://www.instagram.com/p/C1KbU4GuFCL/?img_index=1 (Peppermint); *Swisher Sweets Purple Swish*, CONVENIENCE STORE NEWS (Oct. 8, 2019), https://csnews.com/swisher-sweets-purple-swish; *Purple Swish*, SWISHER SWEETS, https://trade.swisher.com/purple-swish/ (last accessed Feb. 20, 2024); Swisher Sweets (@SwisherSweets), TWITTER (July 18, 2019, 12:01 PM), https://twitter.com/SwisherSweets/status/1151884758089117697 (Passion Fruit); Swisher Sweets (@SwisherSweets), TWITTER (Aug. 4, 2018, 5:00 PM), https://twitter.com/SwisherSweets/status/1025894282803273730 (Coco Blue); Swisher Sweets (@SwisherSweets), TWITTER (Feb. 6, 2018, 6:18 AM), https://twitter.com/SwisherSweets/status/960880462506938369 (Maui Pineapple).

Figure 3: Swisher Sweets (@swishersweets), INSTAGRAM (Dec. 22, 2023), https://www.instagram.com/p/C1KbU4GuFCL/?img_index=1.

Some of these products are marketed as "Limited Edition" to create excitement and anticipation around the launch of a new variety. And the buzz has succeeded in driving cigar sales. As one article in a convenience store trade magazine stated, "[m]uch of the new volume in the [cigar] category comes from flavor launches" and convenience stores "are the biggest sector that the cigar companies use to launch new flavors and limited-time offers (LTOs)."[24]

Swisher has also targeted youth through event sponsorship, pricing practices, and advertising, including on social media. For example, in June 2019, the company hosted the Swisher Sweets Summer Twist Yacht Party, an event featuring celebrities popular among youth and young adults.[25] The party attendees included former Disney Channel actress Bella Thorne, Chanel West

[24] Howard Riell, *Cigar Category Braces Against Proposed Flavor Bans*, CSTORE DECISIONS (Nov. 14, 2022), https://cstoredecisions.com/2022/11/14/cigar-category-braces-against-proposed-flavor-bans/.

[25] Swisher Sweets Artists Project, *Summer Twist Yacht Party*, YOUTUBE (June 29, 2019), https://www.youtube.com/watch?v=b-OK5PC2cPY.

Coast from MTV's *Ridiculousness*, Justina Valentine from MTV's *Wild N Out*, and Shaquille O'Neal, and Swisher posted extensively about the event on its social media accounts.[26]

Figure 4: Summer Twist Party. Swisher Sweets (@swishersweets), INSTAGRAM (June 21, 2019), https://www.instagram.com/p/By-60bEnU53/.

Swisher has also operated a so-called "Artist Project," in which it promotes its brand at concerts, sponsors or features well-known musical artists like Cardi B, and holds pop-up music events in convenience stores that are promoted on its website and social media.[27] These prominent sponsorships expose a much wider audience to Swisher branding and products through tagging profiles and cross-posting on event-related social media accounts that would not normally show tobacco product content. For instance, Swisher Sweets sponsored Shaquille O'Neal's Fun House

[26] *E.g.*, *Id.*; Swisher Sweets (@swishersweets), INSTAGRAM (July 2, 2019), https://www.instagram.com/p/Bzbd4rqH-I9/; Swisher Sweets (@swishersweets), INSTAGRAM (July 1, 2019), https://www.instagram.com/p/BzY2FWwgb9h/; Swisher Sweets (@swishersweets), INSTAGRAM (June 26, 2019), https://www.instagram.com/p/BzMLJ8OAe0g/; Swisher Sweets (@swishersweets), INSTAGRAM (June 23, 2019), https://www.instagram.com/p/BzEfic7gXB1/; Swisher Sweets (@swishersweets), INSTAGRAM (June 22, 2019), https://www.instagram.com/p/BzBG8ulgof7/; Swisher Sweets (@swishersweets), INSTAGRAM (June 21, 2019), https://www.instagram.com/p/By_mQamg0vw/; Swisher Sweets (@swishersweets), INSTAGRAM (June 21, 2019), https://www.instagram.com/p/By-qpUvAfEh/.

[27] *See, e.g.*, *Artist Project*, SWISHER SWEETS, https://ap.swishersweets.com/ (last accessed Feb. 16, 2024); Ollie Ganz et al., *Swisher Sweets 'Artist Project': using musical events to promote cigars*, 27 TOBACCO CONTROL e93 (2018), https://pubmed.ncbi.nlm.nih.gov/29439208.

concert in Miami in 2020, meaning the cigar brand was visible to all attendees. Swisher Sweets' Instagram posts were also tagged with the official Shaq's Fun House account and vice-versa, meaning followers of Shaq's Fun House, including those who did not use tobacco products and possibly youth, were exposed to Swisher marketing.[28]

Swisher's pricing strategies also encourage youth consumption. A study analyzing 2013 data from California found that Swisher Sweets cigarillos cost significantly less in census tracts with higher proportions of school-aged youth and young adults.[29] Moreover, Swisher Sweets' cigarillos are often sold in packs of 2 cigarillos and stamped with price promotions such as "2 for 99¢" or "Save on 2 Cigars," which is significant because young adults show the strongest intentions to buy and smoke cigarillos that are in smaller pack sizes and sold at lower prices.[30] The fact that youth are more inclined to purchase cigars sold in smaller pack sizes also shows that it was entirely reasonable and certainly not "illogical" (Pl's. Mot. 26) for FDA to treat Swisher cigars that are sold in different quantities (e.g., 2-pack vs. 5-pack) as separate products for premarket review purposes. As this Court has recognized, the pack size impacts whether a product "raise[s] different questions of public health," 21 U.S.C. § 387j(a)(3)(A)(ii), than a pre-existing tobacco product. *Philip Morris USA, Inc. v. FDA*, 202 F. Supp. 3d 31, 55-57 (D.D.C. 2016) (holding that "a change in product quantity results in a new tobacco product that is subject to premarket review"

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[28] *E.g.*, Shaq's Fun House (@shaqsfunhouse), INSTAGRAM (Feb. 2, 2020), https://www.instagram.com/p/B8EuyKhAhGu/?img_index=5; Swisher Sweets (@swishersweets), INSTAGRAM (Feb. 2, 2020), https://www.instagram.com/p/B8EkXwfH74C/; Shaq's Fun House (@shaqsfunhouse), INSTAGRAM (Feb. 6, 2020), https://www.instagram.com/p/B8Ouc75DCrm/.

[29] Lisa Henriksen et al., *Neighborhood Variation in the Price of Cheap Tobacco Products in California: Results From Healthy Stores for a Healthy Community*, 19 NICOTINE & TOBACCO RES. 1330, 1334 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5896445/.

[30] Darren Mays et al., *Tobacco minimum packaging policy to reduce cigarillo use among young people: Results of an experimental study*, TOBACCO CONTROL 1, 6, (2022), https://pubmed.ncbi.nlm.nih.gov/35840318/.

under the TCA in part "[b]ecause of the significant effect that changes in product quantity size can have on the behavior of youth.").

Swisher's marketing—both at retail and on social media—also targets youth. At the retail level, a survey of cigar advertisements at 530 California retailers selling tobacco near middle and high schools (median distance of 0.35 miles) found that one in five cigar ads were for Swisher Sweets and most of those ads were for flavored cigars.[31] Relatedly, an analysis of exterior storefront advertisements at tobacco retailers in New York City found that cigar ads are often placed on the door of stores and at heights below three feet—low enough for young children to see.[32] Among adults and youth, higher perceptions of exposure to cigar marketing are associated with higher odds of daily cigar smoking.[33]

On social media, Swisher has particularly targeted young people of color and young women. An analysis of Swisher Sweets' posts on Instagram between 2013 and 2020 found that most of the images of people were Black young adults.[34] Similarly, a study looking at TikTok video content found that posts about Swisher Sweets were more likely to show young adults who were Black or Asian and female compared to posts about large cigars.[35] Influencers posting about

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[31] Kymberle L. Sterling et al., *Flavors and Implied Reduced-Risk Descriptors in Cigar Ads at Stores Near Schools*, 23 NICOTINE & TOBACCO RES. 1895, 1896-1897 (2021), https://pubmed.ncbi.nlm.nih.gov/34214176/.

[32] Daniel P. Giovenco et al., *Characteristics of storefront tobacco advertisements and differences by product type: A content analysis of retailers in New York City, USA*, 123 PREVENTIVE MED 204, 206 (2019), https://pubmed.ncbi.nlm.nih.gov/30930262/.

[33] Sarah D. Kowitt et al., *Objective and perceived measures of tobacco marketing are uniquely associated with cigar use*, 32 TOBACCO CONTROL 428, 432 (2023), https://pubmed.ncbi.nlm.nih.gov/34615738/.

[34] Jennifer Cornacchione Ross et al., *What Cigarillo Companies are Putting on Instagram: A Content Analysis of Swisher Sweets' Marketing from 2013 to 2020*, 25 NICOTINE & TOBACCO RESEARCH 755, 760 tbl.4 (2023), https://doi.org/10.1093/ntr/ntac255.

[35] Jiaxi Wu et al., *The Impact of Influencers on Cigar Promotions: A Content Analysis of Large Cigar and Swisher Sweets Videos on TikTok*, 19 INT'L J. ENVTL. RES. & PUB. HEALTH 7064, 7072 (2022), https://doi.org/10.3390/ijerph19127064.

Swisher Sweets were also more likely to be younger and female compared to influencers for other cigars.[36] By depicting certain types of people in their social media posts, companies signal to viewers the type of people who should use their products. Thus, featuring more people of color—particularly Black and Asian young people—indicates that Swisher is targeting those populations to use its cigars. Swisher Sweets' Instagram posts also used common marketing tactics such as party and concert promotions, sweet flavors, and celebrity participation, to associate its products with an aspirational lifestyle,[37] and some TikTok posts featuring Swisher Sweets used Cardi B's song "Swisher Sweets" as background music.[38]

The result of this proliferation of flavored cigars directed at the youth market has been predictable and troubling. Despite Swisher's contention that cigar use decreased among high school students between 1997-2013 (Pl's. Mot. 3-4), more recent data shows that cigar usage among all high school students (1.8%) now hovers near cigarette usage (1.9%).[39] In November 2023, the Centers for Disease Control and Prevention reported that 280,000 high school students currently used cigars.[40] In 2021 (the most recent year with available data), an estimated 60,000 high school students who smoked cigars did so frequently (20 of the preceding 30 days).[41] According to the 2022 National Survey on Drug Use and Health, more than 700 persons under the age of eighteen smoke their first cigar each day.[42] This trend also persists in the young adult

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[36] *Id.*
[37] Ross et al., *supra* note 34, at 757-60.
[38] Wu et al., *supra* note 35, at 7073.
[39] Birdsey et al., *supra* note 16, at 1178 tbl.2.
[40] *Id.*
[41] Andrea S. Gentzke et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 1, 20 tbl.4 (2022), https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.
[42] *Table 4.10A—Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to Age 18, Prior to Age 21, and at Age 21 or Older; Numbers in Thousands,*

population (18-25 year-olds), with cigars being the most common type of tobacco product initiated during young adulthood.[43]

As noted earlier, much of Swisher's marketing appears directed at Black young adults or people of color. Many studies have documented greater cigar availability and more cigar marketing, including for flavored cigars and price promotions, in neighborhoods with higher percentages of Black residents.[44] Thus, it is not surprising that Black and Hispanic high schoolers smoke cigars at higher rates than white non-Hispanic high schoolers.[45] Analysis of longitudinal PATH data found that non-Hispanic Black young adults had higher odds of initiating and progressing cigarillo use at younger ages compared to non-Hispanic White young adults.[46]

3. Cigar smoking is a significant public health concern.

The evidence amassed and considered by the FDA for the Deeming Rule establishes unequivocally that cigar smoking presents a significant public health risk, both to minors and

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2021 and 2022, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (2023), https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables (Cigars are defined as cigars, cigarillos, or little cigars).

[43] Cristine D. Delnevo et al., *The Effect of Cigarillo Packaging Characteristics on Young Adult Perceptions and Intentions: An Experimental Study*, 18 INT'L J. ENVTL. RES. & PUB. HEALTH 4330, 4330 (2021), https://pubmed.ncbi.nlm.nih.gov/33921793/ (citing 2019 National Survey on Drug Use and Health data). Since the minimum age for sale of tobacco products is now twenty-one under federal law, the young adult category now includes many underage consumers.

[44] *E.g.*, Shyanika W. Rose et al., *Inequitable Distribution of FTP Marketing by Neighborhood Characteristics: Further Evidence for Targeted Marketing*, 24 NICOTINE & TOBACCO RES. 484, 488 (2022), https://pubmed.ncbi.nlm.nih.gov/34687204/; Amanda Y. Kong et al., *Neighborhood Disparities in the Availability, Advertising, Promotion, and Youth Appeal of Little Cigars and Cigarillos, United States, 2015*, 22 NICOTINE & TOBACCO RES. 2170, 2173 (2020), https://pubmed.ncbi.nlm.nih.gov/31917833/; Jennifer Cantrell et al., *Marketing Little Cigars and Cigarillos: Advertising, Price, and Associations With Neighborhood Demographics*, 103 AM. J. PUB. HEALTH 1902, 1905 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3780734/.

[45] Birdsey et al., *supra* note 16, at 1178 tbl.2.

[46] Baojiang Chen et al., *Age of initiation of cigarillo use among young adults: Findings from the Population Assessment of Tobacco and Health (PATH) study, 2013-2017*, 17 PLOS ONE 1, 14 (2022), https://pubmed.ncbi.nlm.nih.gov/35358201/.

adults. As the FDA found, "[a]ll cigars pose serious negative health risks." 81 Fed. Reg. at 29,020. In 2010 alone, "regular cigar smoking was responsible for approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older." *Id.*

"All cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users," as well as "other adverse health effects, such as increased risk of heart and pulmonary disease," "a marked increase in risk for chronic obstructive pulmonary disease (COPD)," a higher risk of death from COPD, and "a higher risk of fatal and nonfatal stroke than nonsmokers." *Id.*

Use of cigars by young people raises unique public health concerns. As the FDA explained, while it "remains concerned about the use of all tobacco products, particularly combusted tobacco products like cigars and cigarettes, . . . [it] remains most concerned about use by youth and young adults given their *unique* susceptibility to the addictiveness of nicotine." *Id.* at 29,023 (emphasis in original); *see also id.* at 29,029 ("The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system."); *id.* at 29,033 ("[N]icotine exposure during adolescence may have lasting adverse consequences for brain development.").

Cigars also can produce significantly more secondhand smoke than cigarettes, and cigar smoke causes negative health effects such as heart disease and lung cancer in nonsmokers. *Id.* at 29,022. In short, as the FDA stated in 2019, "[c]igars are associated with significant risk and provide no public health benefit."[47]

[47] FDA, Draft Guidance, *supra* note 3, at 16.

Compounding the health harms and use rates is the problem that many people perceive, incorrectly, that cigars are less harmful than cigarettes,[48] and these misperceptions are associated with an increased likelihood of cigar use.[49] In the 2014 proposed Deeming Rule, FDA specifically noted that "youth perceive cigars in a more positive light than cigarettes and believe cigars are more natural and less harmful; and some do not realize that cigars contain nicotine. In addition, in a focus group of African-American youth aged 14 to 18, researchers found that the participants were not well versed in the harms caused by smoking cigars." 79 Fed. Reg. at 23,158. Moreover, people often believe that flavored cigars are less harmful than unflavored cigars and cigarettes.[50] A study found that non-Hispanic Black and Hispanic adults were more likely than non-Hispanic white adults to believe flavored cigars were less harmful, which could account for disparities in cigar use.[51] Exempting Swisher's cigars from FDA review would perpetuate the misperception that cigars are less harmful than cigarettes.

In sum, the injunction that Swisher seeks would extend the period during which its new flavored cigar products may remain on the market without marketing authorization—in contravention of the TCA and with great damage to public health.

CONCLUSION

For these reasons, the court should grant Defendants' cross-motion for summary judgment and deny Plaintiff's summary judgment motion.

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[48] Amy L. Nyman et al., *Little Cigars and Cigarillos: Users, Perceptions, and Reasons for Use*, 2 TOBACCO REGULATORY SCI. 239 (2016), https://pubmed.ncbi.nlm.nih.gov/27413772/; Kymberle L. Sterling et al., *The Most Natural Tobacco Used: A Qualitative Investigation of Young Adult Smokers' Risk Perceptions of Flavored Little Cigars and Cigarillos*, 18 NICOTINE & TOBACCO RES. 827, 831 (2016), https://pubmed.ncbi.nlm.nih.gov/26175458/.

[49] Kymberle L. Sterling et al., *Risk Perceptions of Little Cigar and Cigarillo Smoking Among Adult Current Cigarette Smokers*, 19 NICOTINE & TOBACCO RES. 1351, 1356-57 (2017), https://pubmed.ncbi.nlm.nih.gov/27659275/.

[50] FDA Scientific Assessment, *supra* note 14, at 17.

[51] *Id.*

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CERTIFICATE OF SERVICE

I hereby certify that on February 28, 2024 the foregoing brief was filed via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

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